



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: November 18, 2009

SUBJECT: Science Review in Support of the Registration of Z112-013, Containing 20% (S)-Methoprene As Its Active Ingredient.

Decision Number:	416614
DP Number:	367144
EPA File Symbol Number:	63823-AR
Chemical Class:	Biochemical
PC Code:	105402
CAS Number:	65733-16-6
Tolerance Exemptions:	40 CFR 180.1033
MRID Numbers:	477956-01 to -09

FROM: Jacob Moore, Chemist /s/ 11/18/09 *Q. J. Moore*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Cheryl Greene, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Management Contract Services Inc. requests registration of Z112-013, which is intended for use as an insect growth regulator preventing adult mosquito emergence. In support of this registration, the registrant has submitted CSFs dated 06/29/09, label, product chemistry data in MRIDs 477956-01 to -02, tier I toxicity data in MRIDs 477956-03 to -08, and product performance data in MRID 477956-09.

(S)-Methoprene
PC Code: 105402

DP Number: 367144
EPA Reg. No: 63823-AR

RECOMMENDATIONS AND CONCLUSIONS

1. CSFs dated 06/29/09 are **UNACCEPTABLE, but upgradable upon resolution of the following:**
 - a. Both CSFs submitted must include total amount and total % by weight.
 - b. The chemical name for (s)-methoprene must be listed.
 - c. The CAS Number for (s)-methoprene must be corrected to '65733-16-6'.
 - d. The nominal certified limits of active ingredient listed on the alternate formulation CSF must be corrected to '21.68' and '20.42' or rationale must be provided justifying the certified limits presented.
 - e. The other components of an inert mixture that are greater than 0.1% of the EP formulation must be listed.¹
 - f. The lower certified limit of an inert ingredient on CSF B must be corrected to '0.90'.²
2. Product chemistry data in MRIDs 4477956-01 to -02 are **UNACCEPTABLE, but upgradable upon resolution of the following:**
 - a. A MSDS from the manufacturer of an inert ingredient must be provided.³
 - b. Descriptions of the mixing vessels and packing materials must be provided.
 - c. Results from storage stability and corrosion characteristics studies must be submitted upon completion.
3. Tier I toxicity data in MRIDs 477956-03 to -08 are **ACCEPTABLE. No additional data are required.**
4. Product performance data in MRID 47795609 are **UNACCEPTABLE, but upgradable upon resolution of the following:**
 - a. The product label does not claim a specific period of control. The efficacy study was done over a 10 day period. The registrant must submit data supporting a specific length of control or label language indicating reapplication upon reemergence of mosquitoes.
 - b. The product performance study was completed under field conditions in a laboratory. A rate equivalent to 0.75 fl oz EP/acre was used. However, the label does not indicate what depth the product is efficacious at. The study currently indicates efficacy at a depth of 1 foot.
 - c. Field studies must be conducted to verify the results found in the laboratory study.
5. **An assessment on non-target effects from the active ingredient to aquatic species through use of the EP cannot be completed at this time.** The registrant must provide data or relevant scientific rationale concerning the environmental concentration (EC) of the active when used according to the label on appropriate aquatic sites.

(S)-Methoprene
PC Code: 105402

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EPA Reg. No: 63823-AR

STUDY SUMMARIES

Introduction

(S)-Methoprene is an insect growth regulator (IGR) with activity against fleas, mosquitoes, horn flies, ants, sciarid flies and stored product pests. The end-use product (EP) Z112-013 is intended for use as an IGR that prevents adult mosquito emergence on rice fields, intermittently flooded noncrop areas, and crop areas including: Vineyards, rice fields, date palm orchards, fruit and nut orchards, berry fields, and bogs. The EP contains 20% (s)-methoprene from either of two registered sources of active ingredient.

Product Chemistry

See Attached DERs. Note the additional comments provided by the secondary reviewer. No impurities are expected to be present in the finished product. As this EP is not produced by an integrated system, a preliminary analysis is not required. The enforcement analytical method provided is HPLC. The description of production and formulation processes is incomplete. Information must be provided on the mixing vessels and packing materials.

Toxicity

See Attached DERs.

<u>Study Type/OPPTS Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u>
Acute Oral Toxicity/OPPTS 870.1100	>5000 mg/kg	IV	47795603
Acute Dermal Toxicity/OPPTS 870.1200	>5050 mg/kg	IV	47795604
Acute Inhalation Toxicity/OPPTS 870.1300	>2.19 mg/L	IV	47795605
Acute Eye Irritation/OPPTS 870.2400	minimally irritating	IV	47795606
Acute Dermal Irritation/OPPTS 870.2500	slightly irritating	IV	47795607
Skin Sensitization/OPPTS 870.2600	not a sensitizer	N/A	47705608

Product Performance

See Attached DER. A study under field conditions was conducted to determine the efficacy of the EP. The study concludes that the product meets the efficacy standards set forth in OPPTS 810.3400. However, several gaps exist between the study conducted and the claims set forth on the label. The study should also be conducted in the field to support conclusions found in the

(S)-Methoprene
PC Code: 105402

DP Number: 367144
EPA Reg. No: 63823-AR

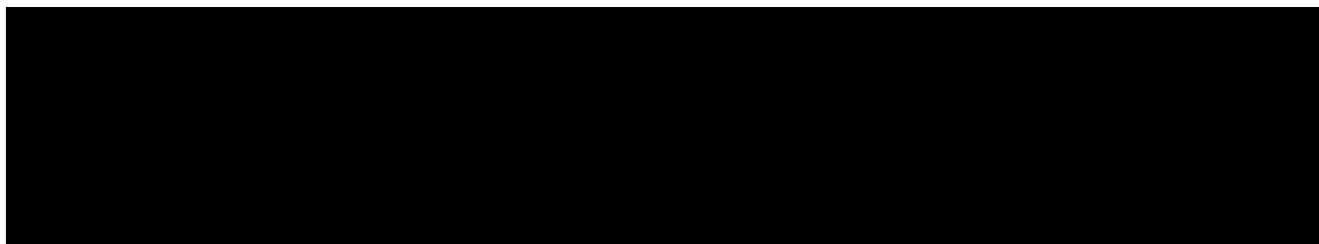
laboratory. More information must be provided on what depth the EP is efficacious at in aquatic environments. The study currently indicates efficacy at a depth of 1 foot.

cc: J. Moore, C. Greene BPPD Chron File, IHAD/ARS
J. Moore, FT, PY-S: 11/18/09

(S)-Methoprene
PC Code: 105402

DP Number: 367144
EPA Reg. No: 63823-AR

CONFIDENTIAL APPENDIX



****Inert ingredient information may be entitled to confidential treatment****

****Manufacturing process information may be entitled to confidential treatment****



13544

R184094

Chemical Name: S-Methoprene

PC Code: 105402

HED File Code: 41500 BPPD Tox/Chem

Memo Date: 11/18/2009

File ID: 00000000

Accession #: 000-00-0135

HED Records Reference Center
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